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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,253	03/22/2004	David C. Baulcombe	616292000110	1920
25225 7590 08/06/2007 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER BOWMAN, AMY HUDSON	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 08/06/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/806,253

Applicant(s)

BAULCOMBE ET AL.

Examiner

Amy H. Bowman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32-37, 39-41, 47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32, 35-37, 39-41, 47 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/491,549.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/2/07, 7/20/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's responses filed 3/1/07 and 5/22/07 have been considered.

Rejections and/or objections not reiterated from the previous office action mailed 10/5/06 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32-37, 39-41, 47 and 49 are pending in the instant application.

This application contains claims 33 and 34 that are drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendments and/or arguments filed 3/1/07, with respect to the rejection(s) of claim(s) under 35 USC 112, 2<sup>nd</sup> paragraph, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the instant amendments.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 3/1/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US

6,753,139 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Neither of the prior-filed applications teach a limitation of characterizing any SRMs which are present in said extract to determine sequence identity of similarity with "any" target gene, as instantly recited.

Furthermore, applicant asserts that support for "preparing a library of genes and identifying those genes in the library that share sequence identity or similarity with any SRMs", as recited in instant claim 41 is located at page 6, lines 5-13 of the instant specification. However, the specification discloses, "the SRMs may be used to identify

and isolate an unknown target. This could be achieved by analyzing the 25 nucleotide fraction of RNA from a plant, tagging it with a marker (e.g. a radioactive one) and then using this radioactive RNA to probe a library of plant genes. This probe will anneal to genes which are undergoing PTGS in the plant, which genes can then be further analyzed or characterised if required." The teaching in the instant specification is clearly directed strictly to plant genes.

Applicant further points to support in originally filed claim 11. However, originally filed claim 11 is not supported by the instant specification. The specification fails to provide proper antecedent basis for the claimed subject matter of originally filed claim 11 (See 37 CFR 1.75(d)(1) and MPEP § 608.01(o)) because the teaching of the specification is specific to plant genes, as explained above.

Therefore, the instant claims are accorded an effective filing date of 3/22/2004, the filing date of the instant application. Should applicant disagree, applicant is encouraged to point to support for each limitation with particularity by page and line number.

### ***Response to Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specifically, there is a cross out on the date line under the signature of David Baulcombe that has not been initialed. Although applicant asserts that there is not a cross-out, but rather a correction to the date to match that abbreviated date, all alterations are required to be initialed, as explained above.

***Response to Arguments--Claim Rejections - 35 USC § 102***

Claims 32, 35-37, 39, 40, 47 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Agrawal et al. (WO 94/01550), as further evidenced by Bridge et al. (Nature Genetics, Vol. 34, No. 3, July 2003, pages 263-264), for the reasons of record as set forth in the office action mailed on 10/5/06.

Applicant asserts that the first step required in instant claim 32 is to analyze a nucleic acid extract to determine the presence or absence of short RNA molecules that are 20-30 nucleotides in length in the extract and that applicants were unable to find any such step in Agrawal.

As explained in the office action mailed on 10/5/06, Agrawal et al. teach detection of target gene inhibition comprising testing oligonucleotides for their ability to inhibit HIV-1 in tissue culture (see example 3). Agrawal et al. teach introduction of the oligonucleotide, followed by production of a nucleic acid extract of the infected sample, and analyzing the extract for gene silencing. The extract taught by Agrawal et al. necessarily contained the short RNA molecules (the sense and antisense strands of the hairpin connected by a linker) that were inserted by the procedure. Since Agrawal et al. determine the presence of gene silencing as a result of the short RNA molecules, the

short RNA molecules of Agrawal et al. are taught to have identity or similarity with a target gene, the gene that is silenced.

Claims 32, 35, 36, 38, 40, and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Baracchini et al. (U.S. 5,801,154), for the reasons of record as set forth in the office action mailed on 10/5/06.

Applicant asserts that Baracchini et al. do not analyze any extracts for short RNA molecules but rather feeds a short antisense molecule to cells to effect gene silencing. It is noted that the instant claims do not exclude an extra step of introducing the SRM into the organism. Simply because Baracchini et al. introduce the antisense oligonucleotide does not mean that Baracchini et al. do not analyze the extract for SRMs.

Baracchini et al. teach a method of inhibiting the expression of a target gene via interfering with target RNA comprising introducing an oligonucleotide having 8 to 30 nucleotides specifically hybridizable with a target nucleic acid that encodes MRP (see claim 26, for example). Importantly, the oligonucleotide-treated cells can be cultured and screened for the desired result (see column 6).

Baracchini et al. teach detection of gene silencing followed by analyzing the extract for the presence or absence of the short RNA molecule and further teach experiments in nude mice. Baracchini et al. teach Northern blot analysis of the effects of oligonucleotides on MRP mRNA levels, wherein the oligonucleotides demonstrated to virtually eliminate target gene expression (see column 11).

Additionally, the oligonucleotides utilized in the method of Baracchini et al. meet the structural limitations of the instant claims and would therefore necessarily act through the instantly recited mechanisms of PTGS and co-suppression.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 35-37, 39-41, 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The claims are directed to the method recited in instant claim 32 wherein step (iv) recites, "characterizing any SRMs which are present in said extract to determine sequence identity or similarity with any target gene". However, the instant specification does not teach a limitation of determining the sequence identity or similarity with "any" target gene, as instantly recited. Therefore, this newly added limitation constitutes new matter.



Therefore, the effective filing date of the instant claims is considered, for purposes of prior art, to be 3/22/04, which is the filing date of the instant application.

A review of the specification does not reveal support for where the instant claim amendment is found. Should applicant disagree, applicants are encouraged to point out with particularity by page and line number where such support might exist for each claim limitation added in the amended claims filed on 3/22/04.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy H Bowman  
Examiner  
Art Unit 1635

AHB

/J. E. Angell/  
Primary Examiner  
Art unit 1635